athenahealth

October 29, 2013

The Honorable Marsha Blackburn
US House of Representatives
217 Cannon House Office Building
Washington, DC 20515

The Honorable Phil Gingrey
US House of Representatives
442 Cannon House Office Building
Washington, DC 20515

The Honorable G.K. Butterfield
US House of Representatives
2305 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
US House of Representatives
2470 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
US House of Representatives
2368 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
US House of Representatives
2182 Rayburn House Office Building
Washington, DC 20515

Dear Representatives,

athenahealth commends your bipartisan collaboration in the introduction of the Software Oversight for Technology Which Advances Regulatory Efficiency (SOFTWARE) Act of 2013. This legislation provides much-needed clarity regarding the oversight of various types of health information technology (health IT).

As many of you know, athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of over 40,000 healthcare professionals in nearly every state. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our cloud platform affords to us and our clients a significant advantage over traditional, static software-based health IT products as we work to realize our company vision of a national information backbone enabling healthcare to work as it should. Our client's successes, exemplified by a Meaningful Use attestation rate more than double the national average, underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

Consistent with the clear intent of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) and the approach laid out in a recent multi-stakeholder effort led by the Bipartisan Policy Center, ***An Oversight Framework for Patient Safety in Health Information Technology***, the SOFTWARE Act appropriately identifies three categories of health IT according to relative risk (medical software, clinical software, and health software) and provides the basis for a new risk-based regulatory framework for clinical software and health software that encourages innovation, increases patient safety, and reduces regulatory burden.

It is imperative that any oversight framework for health IT distinguishes technologies that present real risks to patients from those that do not present such risks. A rational framework will protect patients while preserving and protecting the ability of industry leaders like athenahealth to innovate and improve our services, providing myriad benefits—including safety benefits—to care providers and their patients.

HEALTHCARE
LEADERSHIP
COUNCIL

November 15, 2013

The Honorable Marsha W. Blackburn
U.S. House of Representatives
217 Cannon House Office Building
Washington, DC 20515-4207

The Honorable Diana DeGette
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515-0601

Dear Representatives Blackburn and DeGette:

The Healthcare Leadership Council (HLC) applauds your recent efforts to drive innovation and ensure patient safety through the *Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act* (H.R. 3033). HLC members recognize the need for regulatory clarity regarding mobile medical applications, clinical decision support tools, electronic health records, and other health care related software. We are pleased to see a bipartisan approach to ensuring continued advances in patient safety and care quality through new technologies and products.

There is universal acceptance that all of those involved in healthcare need to find ways to achieve better outcomes, advance wellness, and contain costs. One avenue toward this progress is the hugely successful innovation currently underway in health information technology. Our members are making real progress in keeping people healthy, successfully combating chronic disease, improving patient outcomes, and maintaining affordability through new ideas, new inventions, and new discoveries.

We appreciate that your effort builds upon the existing work of the multi-stakeholder Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup, as well as the respected research of the Institute of Medicine, and the expertise of the Food and Drug Administration (FDA). No organization has more experience ensuring that medical devices are safe for patients than the FDA, and we acknowledge the importance of their expertise as we consider the best approaches for new technologies. We also understand and support the continued collection of input and refinements from other stakeholders as this groundbreaking legislation moves forward.

As a collaborative group of CEOs from all disciplines of American healthcare, HLC members support a continued focus on ensuring all perspectives are acknowledged as Congress considers this important issue. HLC and its members stand ready to work with you and your colleagues on both sides of the aisle to ensure that any changes drive continued innovation that increases value, improves quality, and advances patient safety.

Sincerely,

Mary R. Grealy
President

November 6, 2013

The Honorable Marsha Blackburn
217 Cannon House Office Building
Washington, DC 20515

Dear Congressman Blackburn:

The Health IT Now Coalition supports your efforts to advance legislation, H.R. 3303, the SOFTWARE Act that would clarify the regulation of medical device and health information technology software. Introducing the bill is an important first step in updating the regulatory framework for new health information technologies. We look forward to working with you to refine the bill as it moves through the legislative process.

Health IT Now is a coalition of organizations that promotes the adoption and use of health information technology (health IT) to lower costs and improve quality, safety and outcomes. Our membership is diverse; it includes healthcare providers, employers, patient advocates, and insurers.

Medical devices have made a significant impact on patient's health and have changed the way patients are treated and healed. These devices are typically discrete machines, with singular and well-defined purposes. Health IT, however, is increasingly used for multiple, novel purposes, and often in a networked environment and in ways developers had not even conceived when the software was written. This creativity is allowing patients, providers and payers to leverage technology to enhance care-coordination and management strategies that improve health outcomes and lower costs. An emerging strategy is the integrated use of mobile medical apps by clinicians and patients with electronic health records and personal health records.

Your bill would refine the types of software the Food and Drug Administration should ensure are safe and effective for use, while ensuring that clinical and health software systems fall outside the FDA review and approval process. We believe this clarity may be helpful in fostering innovation by better defining the rules of the regulatory approval process.

This is why we support your effort to cultivate a dialogue between Congress and the Administration, and to solicit input from effected stakeholders. We believe we should all work together to reform the device approval process to promote innovation and patient safety. We look forward to working with you as the legislation is refined and moves through the Congressional process.

Sincerely,

Joel C. White
Executive Director

Health IT Now Coalition▪ 750 9th Street, NW, Suite 750▪ Washington, D.C. 20001
(202) 559-0205 *main*▪ www.healthitnow.org

Peter B. Davidson
Senior Vice President
Federal Government Relations

1300 I Street, NW, Suite 400 West
Washington, DC 20005

Phone: 202-515-2512
peter.b.davidson@verizon.com

November 12, 2013

The Honorable Marsha Blackburn
217 Cannon House Office Building
Washington, DC 20515

The Honorable Phil Gingrey
442 Cannon House Office Building
Washington, DC 20515

The Honorable G. K. Butterfield
2305 Rayburn HOB
Washington, DC 20515

The Honorable Gene Green
2470 Rayburn HOB
Washington, DC 20515

The Honorable Diana DeGette
2368 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
2182 Rayburn House Office Building
Washington, DC 20515

Dear Representatives:

Verizon is encouraged by and supports your efforts to provide clarity around the regulation of medical devices and health information technology. Verizon believes patient safety is critical and should be the driving force behind any federal legislation. The SOFTWARE Act (HR 3303) reflects this and is a positive step towards providing certainty for millions of application developers, device makers and entrepreneurs looking to enter this dynamic market place. More importantly this Act would help speed the development of innovative technology to ultimately drive better outcomes for patients.

Verizon, through its health care practice group, offers a comprehensive portfolio of managed IT and consulting services for the health care industry. As a technology solutions provider, Verizon understands first-hand the tremendous opportunities for improvements in health care that result from innovation in information technology. Innovations in technology are enabling greater access to care, reducing costs and improving health outcomes for millions of patients across the country.

However, an outmoded regulatory structure threatens the improvements that technology can bring to the delivery, cost and access of health care. Your bipartisan legislation will provide clarity on the types of software that the Food and Drug Administration should regulate while making sure that information management systems fall outside the FDA review and approval process. This clarification will provide more certainty for the FDA, device manufacturers and entrepreneurs to know what is within the FDA's purview and what is not. We believe your bill is a step in the right direction for addressing the gaps in existing law.

We thank you for your leadership on this important issue and look forward to working with you and your colleagues on ensuring that a proper regulatory framework is in place that fosters innovation and promotes access to potentially life-saving technologies.

Sincerely,

Application Developers Alliance

November 18, 2013

The Honorable Marsha Blackburn
Member (R-TN)
House of Representatives
217 Cannon House Office Building
Washington, D.C. 20515

Re: H.R. 3303 - Sensible Oversight for Technology, which Enhances Regulatory Efficiency (SOFTWARE) Act

Dear Representative Blackburn:

The Application Developers Alliance, on behalf of our more than 30,000 app developers and 150 corporate members, is pleased to express our appreciation for your introduction of H.R. 3303, the Sensible Oversight for Technology, which Enhances Regulatory Efficiency (SOFTWARE) Act. This bipartisan bill will provide additional regulatory clarity for developers of mobile medical apps.

As you know, app developers create innovative products and services that help patients, caregivers and physicians. The Food and Drug Administration (FDA) recently recognized these benefits when it issued its Final Guidance on Mobile Medical Apps. In the Guidance, the FDA clarified its tailored, risk-based approach to regulating mobile medical apps, an approach that is reflected in your legislation. The Alliance provided comments to the FDA, and was particularly pleased that the agency provides specific examples on its website of apps that it will regulate as well as those that it does not plan to regulate.

A significant benefit of your legislation is the certainty that it provides app developers, and the patients and providers that they serve. Additionally, by eliminating the application of the medical device tax to mobile medical apps, your legislation promotes innovation and investment in new apps that will benefit even more patients.

The Alliance is ready to work with you and your colleagues, and with the FDA, to promote a regulatory environment that encourages innovation and improves Americans' health. We welcome your legislation and look forward to the opportunity for hearings and its rapid consideration.

Sincerely,

Jon Potter
President

1025 F St, NW, Ste 720 | Washington, DC | 20004
appdevelopersalliance.org

Fostering Innovation in Health IT

IBM Position

Health IT has great promise to tremendously improve the quality, cost-effectiveness, and patient experience of care. IBM strongly supports the bi-partisan Blackburn-DeGette SOFTWARE Act to foster technological innovation by creating regulatory clarity.

We encourage you to co-sponsor H.R. 3303.

H.R. 3303 – The SOFTWARE Act

The Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act clarifies the statute of the FDA to focus regulation on high-risk "medical" software and removes low-risk "clinical" and "health" software from FDA's purview.

- Medical software is intended to treat or cure disease without the involvement of a clinician. Software in pacemakers and insulin pumps are examples.
- Clinical software does not directly impact patient care. It is intended to help physicians analyze data as they determine how to treat the patient. IBM Watson is an example.
- Health software refers to administrative tools that gather data, such as calorie counters.

It also calls for Congress and the Administration to establish a risk based framework for the later two groups.

Bill Benefits

- Encourages the continued development of evidence-based technologies that help doctors draw on far more evidence than any of them can possibly access on their own.
- Focuses the FDA's regulatory energies to software and devices that directly affect patients, without interfering with doctors' ability to access evidence-based insights.
  - All software is not the same; there should not be a one size fits all approach.
  - Current FDA regulatory framework is decades old; built for discrete devices manufactured at a single site, physically shipped to distributors/users, modified relatively infrequently, and often not interacting with other devices.
- Ensures that U.S. consumers have access to the most innovative, individualized, evidence supported medicine.

Health of Our Nation at Risk – Act Today

- Healthcare is a data rich but innovation poor environment.
  - Every 5 years, medical information doubles, but 81% of physicians spend less than 5 hours a week reading medical journals.
  - Primary care physicians spend an average of 10.7-18.7 minutes face-to-face with each patient per visit.
  - An estimated 15% of diagnoses are inaccurate or incomplete.
- IBM Watson's advanced analytics combined with cognitive computing and natural language processing can help doctors efficiently access and make use of all this data.
- Congress has the prerogative to – and should – act to legislatively clarify the health IT environment. We need the benefits of innovations in health IT, now.